DETAILED ACTION

Status of Application

1. Applicant's election without traverse of Group III (claims 23-26) in the reply filed on 3/4/08 is acknowledged.

2. Claims 1-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim.

3. Claims 23-26 are included in the prosecution.

Information Disclosure Statement

4. The information disclosure statement (IDS) submitted on 4/8/05 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97 and 1.98. Accordingly, the examiner is considering the information disclosure statement.

See attached copy of PTO-1449.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hashimoto et al. (WO 02/44167).

The claimed invention is a process for producing an amorphous optically active isomer of lansoprazole which comprises keeping hydrated crystals of optically active isomer (R-isomer) of lansoprazole at about 20 to about 100°C.

Hashimoto teaches a method of producing (R)-lansoprazole (Abstract). The (R) - lansoprazole produced by the method may be a crystal of (R)-lansoprazole and may be a hydrate. "The "hydrate" includes 0.5 hydrate to 5.0 hydrate. More preferred is 0.5 hydrate, 1.0 hydrate and 1.5 hydrate" (Page 8, lines 15-23). "The thus-obtained crystal may be used as it is, or dried ... The "drying" includes, for example, vacuum drying, through-flow drying, drying by heating, air drying and the like" (Page 14, lines 1-5).

Hashimoto does not expressly teach the process of drying the hydrate of (R)-lansoprazole in the temperature range of about 20 to about 100°C.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the method of producing and drying a hydrate of (R)-lansoprazole, as taught by Hashimoto, and perform the drying at a temperature range of about 20 to about 100°C during the process of routine experimentation, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because during the process of routine experimentation one would store the (R)-lansoprazole at room temperature or would dry the (R)-lansoprazole, which would lead to the formation of an amorphous (R)-lansoprazole.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed

invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Regarding instant claim 23, the process for producing an amorphous optically active isomer of lansoprazole which comprises keeping hydrated crystals of optically active isomer (R-isomer) of lansoprazole at about 20 to about 100°C would have been obvious over the method of producing and drying a hydrate of (R)-lansoprazole, as taught by Hashimoto (Page 8, lines 15-23 and Page 14, lines 1-5).

Regarding instant claim 24, the limitation of heating at about 40 to about 80°C would have been obvious over the method of drying a hydrate of (R)-lansoprazole, as taught by Hashimoto (Page 14, lines 1-5). One with ordinary skill in the art would modify the storage or drying temperature of a hydrate of (R)-lansoprazole during the process of routine experimentation and the recited temperature range would have been an obvious variant unless there is evidence of criticality or unexpected results.

Regarding instant claim 25, the limitation of 0.5 to 1.5 hydrate crystals of (R)-lansoprazole would have been obvious over the 0.5 hydrate, 1.0 hydrate and 1.5 hydrate taught by Hashimoto (Page 8, lines 15-23).

Regarding instant claim 26, the limitation of the keeping of the temperature under reduced pressure or under ventilation would have been obvious over the vacuum drying, through-flow drying, drying by heating, and air drying taught by Hashimoto (Page 14, lines 1-5).

7. Claims 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fujishima et al. (WO 00/78745).

Fujishima teaches isolation of (R)-2-[[[3-methyl-4-(2,2,2-trifluoroethoxy)-2-pyridinyl]methyl]sulfinyl]-1H-benzimidazole (R(+)-lansoprazole) where the filtrate was evaporated to dryness to yield R(+)-lansoprazole as an amorphous substance (Page 13, line 30 to Page 14, line 16). The starting material is a crystal of R(+)-lansoprazole which may be a hydrate (Page 2, lines 32-34). The hydrate may be a 0.5 hydrate to 5.0 hydrate (Page 2, line 35 to Page 3, line 3).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the method of evaporating a hydrate of R(+)-lansoprazole to dryness, as taught by Fujishima, and perform the drying at a temperature range of about 20 to about 100°C during the process of routine experimentation, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because during the process of routine experimentation one would store the (R)-lansoprazole at room temperature or would dry the (R)-lansoprazole, which would lead to the formation of an amorphous (R)-lansoprazole.

Regarding instant claim 23, the process for producing an amorphous optically active isomer of lansoprazole which comprises keeping hydrated crystals of optically active isomer (R-isomer) of lansoprazole at about 20 to about 100°C would have been obvious over the method of evaporating to dryness a hydrate of R(+)-lansoprazole, as taught by Fujishima (Page 13, line 30 to Page 14, line 16, Page 2, lines 32-34).

Regarding instant claim 24, the limitation of heating at about 40 to about 80°C would have been obvious over the method of evaporating to dryness a hydrate of R(+)-lansoprazole, as taught by Fujishima (Page 13, line 30 to Page 14, line 16). One with ordinary skill in the art would modify the storage or drying temperature of a hydrate of (R)-lansoprazole during the process of routine experimentation and the recited temperature range would have been an obvious variant unless there is evidence of criticality or unexpected results.

Regarding instant claim 25, the limitation of 0.5 to 1.5 hydrate crystals of (R)-lansoprazole would have been obvious over the 0.5 hydrate, 1.0 hydrate and 1.5 hydrate taught by Fujishima (Page 2, line 35 to Page 3, line 3).

Regarding instant claim 26, the limitation of the keeping of the temperature under reduced pressure or under ventilation would have been obvious over the evaporating to dryness taught by Fujishima (Page 13, line 30 to Page 14, line 16). One of ordinary skill in the art would use the available methods of drying during the process of routine experimentation, including evaporation or air drying, drying by increasing the temperature, and maintaining the temperature under reduced pressure.

Conclusion

8. No claims are allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aradhana Sasan whose telephone number is (571) 272-9022. The examiner can normally be reached Monday to Thursday from 6:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Aradhana Sasan/
Examiner, Art Unit 1615

/Michael P Woodward/
Supervisory Patent Examiner, Art Unit 1615